

**REMARKS/ARGUMENTS**

Claims 68, 138, 142 and 144-186 are pending in the instant application. Claims 68, 138, 142, and 148 have been amended. Claim 144 has been cancelled. Accordingly, claims 68, 138, 142 and 145-186 will remain pending upon entry of the instant amendment. *Applicants respectfully submit that these claims are drawn solely to subject matter that was indicated as allowable in the Non-Final Office Action mailed from the United States Patent and Trademark Office on August 29, 2005.*

The Examiner's statements set forth in the outstanding Office Action regarding the enablement of the method of inhibiting epileptogenesis or treating a convulsive disorder by the instant specification are gratefully acknowledged. Claims 68, 138, and 142 have been amended to recite the limitation of claim 144, and dependent claim 148 has been amended accordingly. Support for the amendment to claims 68, 138, 142, and 148 may be found at least, for example, in the specification and in previous claims 68, 138, 142, 144 and 148. *No new matter has been added.*

Amendment and cancellation of the claims at any time during the prosecution of this application are not to be construed as acquiescence to any of the objections/rejections set forth in the instant Office Action or any previous Office Action, and are done solely to expedite prosecution of the application. Applicants submit that claims were not added or amended during the prosecution of the instant application for reasons related to patentability. Applicants reserve the right to pursue the claims as originally filed, or similar claims, in this or one or more subsequent patent applications.

***Rejection under 35 U.S.C. § 112******Rejection of Claims 68, 138, 142, and 144-162 under 35 U.S.C. § 112, First Paragraph***

Claims 68, 138, 142, and 144-162 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not reasonably providing enablement for a method of inhibiting epileptogenesis or treating a convulsive disorder using all types of substituted  $\beta$ -amino anionic compounds wherein the anionic group is sulfate, sulfonate, sulfinic, sulfamate,

tetrazolyl, phosphate, phosphonate, phosphinate, or phosphorothioate moiety. Applicants respectfully disagree with this analysis. However, solely to expedite prosecution, Applicants have amended claims 68, 138, 142 to recite the limitation of claim 144, *i.e.*, that the anionic group is a carboxylate. Accordingly, Applicants submit that the rejection as described on pages 2 and 3 of the Office Action is moot and request reconsideration and withdrawal of the rejection. Moreover, Applicants reiterate that the instant amendments are not to be construed as acquiescence to the rejection set forth in the instant Office Action, and are made solely to expedite prosecution of the application.

On page 4 of the Office Action, the Examiner stated that the term “inhibition of epileptogenesis” is explained in the specification as a method that causes “changes in brain tissue which result in epileptic seizures”. Applicants wish to clarify that epileptogenesis is the process whereby normal brain is transformed into a state susceptible to seizures (see page 1, lines 22-26). Thus the term “inhibition of epileptogenesis” refers to preventing, slowing, halting, or reversing the process of epileptogenesis (see page 13, lines 35-37).

Also on page 4 of the Office Action, the Examiner was of the opinion that the specification does not provide sufficient disclosure how these methods are carried out using the entire genus of compounds of the claims, because the specification does not set forth the synthetic methods to prepare the compounds of the claims. Applicants respectfully disagree with this analysis, and moreover note that the claims are directed to methods of inhibiting epileptogenesis and methods for treating a convulsive disorder, not to methods of chemical synthesis. However, solely to expedite prosecution and as described above, Applicants have amended claims 68, 138, 142 to recite that the anionic group is a carboxylate. In view of the Examiner’s statement on page 3, line 11-13 that “... the specification provides the essential starting materials to prepare the  $\beta$ -amino anionic compounds of the instant claims wherein the anionic group is carboxylate,” Applicants submit that the instant claims are in condition for allowance and request reconsideration and withdrawal of the rejection.

On page 4, lines 5-7 of the Office Action, the Examiner was of the opinion that the specification does not provide any guidance regarding how to identify a subject “in

need of the claimed method of inhibiting or treatment”. Applicants respectfully direct the Examiner’s attention to page 1, lines 26-36 wherein epileptogenesis is described as follows:

“Epileptogenesis is a two phase process. Phase I epileptogenesis is the initiation of the epileptogenic process prior to the first seizure, and is often the result of a stroke, disease (e.g., meningitis), or trauma, such as an accidental blow to the head or a surgical procedure performed on the brain. Phase 2 epileptogenesis refers to the process during which brain which is already susceptible to seizures, becomes still more susceptible to seizures of increasing frequency and/or severity.”

Applicants submit that it would be clear to one skilled in the art, in light of the instant specification, to determine subjects “in need of” the claimed method of inhibiting or treatment, for example, which are identifiable from this teaching, particularly in view of the high level of skill in the art to which the invention pertains. As such, withdrawal of the rejection and reconsideration are respectfully requested.

On page 4, lines 7-9, the Examiner stated that the biological activity of the exemplified compounds is disclosed as Not Available (NA) or as Inactive in Table 3 and there is nothing in the disclosure regarding how this data correlates to the claimed method of inhibition of treatment. Applicants point out that the last column of Table 3 on pages 59-68 refers to a standard anticonvulsant test. This column is labeled as “biological testing” and has a superscripted descriptor “d” that is defined on pages 59, 62, 64, and 68 as filed as, “Using pilocarpine, compound is active in rat at 100 mg/kg, or inactive.” Such standard anticonvulsant tests are described in a scientific journal article by Horton, R.W. *et al.*, Eur. J. Pharmacol. (1979) 59: 75-83 which is referenced at page 26, lines 34-36. Compounds that were found to have activity in the anticonvulsant test per Example 6 are listed at page 69, lines 31-37. Such compounds were tested using the spontaneous recurrent seizure (“SRS”) model for Phase I epileptogenesis described in Example 4, with results listed at page 69, lines 26-30. A summary statement regarding the activity of

the  $\beta$ -amino acids as anti-ictogenic compounds and anti-epileptogenic agents is found on page 70, lines 1-2. In view of the foregoing, Applicants request withdrawal of the rejection and reconsideration.

The Examiner stated on page 4, lines 9-12, that the data provided is insufficient such that no reasonable extrapolation could be made by one skilled in the art regarding the activity of the compounds of the entire genus of the previous claims. Applicants traverse this rejection. Applicants are under no obligation to test each and every possible compound falling under the claimed genus. Given the level of skill in the art pertaining to the invention and the teachings of the present application, one of ordinary skill in the art could easily design compounds in accordance with the specification and the instant claims, *e.g.*, compounds which block both the NMDA receptor and the GABA receptor, and determine, employing screening techniques known to the ordinarily skilled artisan at the time the instant application was filed, those compounds which have activity. Notwithstanding and as described above, Applicants have restricted the compounds recited by the claims to those having a carboxylate moiety as suggested by the Examiner, in order to expedite prosecution. In view of the foregoing, Applicants request withdrawal of the rejection and reconsideration.

Claim 144 has been cancelled; accordingly, Applicants submit that the rejection of claim 144 is moot and request withdrawal of the rejection of previous claim 144.

Claims 145-162 are believed to be allowable since they each depend, directly or indirectly, from allowable claims 68, 138, or 142.

Applicants respectfully request withdrawal of the rejection of claims 68, 138, 142, and 144-162 under 35 U.S.C. §112, first paragraph, and favorable reconsideration.

*Allowable Subject Matter*

Applicants appreciate the Examiner's acknowledgement that the subject matter of claims 163-186 is allowable. Claims 163-186 are believed to be allowable since they each depend from allowable claims 68, 138, and 142.

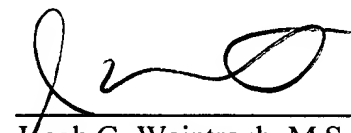
CONCLUSION

In view of the foregoing amendments and remarks/arguments presented, favorable reconsideration and withdrawal of all rejections, and allowance of this application with all pending claims 68, 138, 142 and 145-186 are requested. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Please charge our Deposit Account No. 12-0080 for any fees that may be due for this Amendment and Response to Non-Final Office Action. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. NCI-006DV1.

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

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